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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,395	09/25/2001	Francis X. Cunningham JR.	P108172-00022	8945

7590 01/21/2004

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EXAMINER

RAMIREZ, DELIA M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/701,395	CUNNINGHAM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 10 November 2003.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-10 is/are pending in the application.  
 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,3-6 and 9 is/are rejected.  
 7) Claim(s) 2 and 10 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 26 October 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.  
 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Status of the Application*

Claims 1-10 are pending.

Applicant's amendment of claims 1-3, amendments to the specification, and addition of claims 9-10 in a communication filed on 11/10/2003, are acknowledged.

This application contains claims 7-8 drawn to an invention non-elected with traverse in Paper No. 10, filed on 3/25/2003. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### *Claim Objections*

1. Claim 2 is objected to due to the recitation of "sequence of one of SEQ ID NO: 23". The term "one of" implies additional sequences. However only SEQ ID NO: 23 is recited. It is suggested that the term "one of" be deleted. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112, First Paragraph*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3-6 remain rejected and newly added claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding the polypeptide of SEQ ID NO: 23, a host cell, and a vector comprising said nucleic acid, does not reasonably provide enablement for a nucleic acid encoding a polypeptide having 85%-90% sequence identity to the polypeptide of SEQ ID NO: 23. The specification does not enable any person skilled in the art to which

it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

4. This rejection has been discussed at length in the Non Final Action mailed on 7/9/2003 and is now applied to newly added claim 9 for the reasons of record.

5. Applicants argue that the specification provides detailed guidance of changes that can be included and submit that while substituting 5-amino acids change product specificity, both of the proteins referred to in the specification (page 9, lines 30-32) retain lycopene  $\epsilon$ -cyclase activity.

6. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection as it applies to claims 1, 3-6 or to avoid the rejection of claim 9. The Examiner acknowledges the teachings of the specification, specifically those related to the carboxy terminus which are responsible for adding 2  $\epsilon$  rings to form  $\epsilon,\epsilon$ -carotene (page 10, lines 5-17). However, the five amino acids responsible for this change in specificity only represent approximately 1% of the total number of amino acids in SEQ ID NO: 23 (529 amino acids). The specification does not provide sufficient information as to which 53-80 (10%-15% variation) amino acids can be modified in the polypeptide of SEQ ID NO: 23 and still retain lycopene  $\epsilon$ -cyclase activity. It is also noted that while the specification discloses that several amino acids can be deleted from the N terminus of the lycopene  $\epsilon$ -cyclases disclosed and still retain lycopene  $\epsilon$ -cyclase activity, the specification does not teach other deletions, insertions and/or substitutions in the lycopene  $\epsilon$ -cyclase of SEQ ID NO: 23 which would result in polypeptides having 85%-90% sequence identity to SEQ ID NO: 23 and the same activity. Furthermore, while one could argue that the teachings of the specification provide sufficient guidance regarding the amino acid modifications that can be made and retain the desired activity, it is noted that while the specificity of the polypeptide of SEQ ID NO: 23 has been disclosed, the specificity of other lycopene  $\epsilon$ -cyclases which may result from deleting several amino acids of the N terminus has not been disclosed. It is noted the specification teaches that while deleting amino acids from the N terminus may not change lycopene  $\epsilon$ -

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cyclase activity, it may change its specificity (page 12, lines 12-15). As such, one of skill in the art would have to go through the burden of undue experimentation in order to determine the actual specificity of the resulting lycopene  $\epsilon$ -cyclases. Therefore, for the reasons set forth above and those already discussed in the Non Final Action, one cannot reasonably conclude that the claimed invention is fully enabled.

*Allowable Subject Matter*

7. Claims 2 and 10 appear to be allowable over the prior art of record but are objected to since they depend upon a rejected base claim.

*Conclusion*

8. Applicant's amendment of claims 1-3 and addition of claims 9-10 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
January 7, 2004

*Rebecca E. Prouty*  
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